REMARKS

Upon entry of the present amendment, claims 1, 3-18, and 20-40 are pending in the instant application. Of these, claims 5-14, 16-17, and 21-37 have been withdrawn from consideration subject to the restriction requirement of May 2, 2007. Pursuant to the Non-Final Office Action of August 1, 2007, elected claims 1-4, 15, and 18-20 stand rejected on both reference and non-reference grounds. In an effort to expedite prosecution, Applicants have amended the claims as follows:

- To distinguish the claimed invention from products of nature, claim 1 has been amended to refer to "The isolated allergen". Support for this amendment is found in the specification as originally filed, particularly at paragraph [0018] of the published application (USPN 2005/0215766 published September 29, 2005)

- Claim 1 has further been amended to recite an isolated allergen consisting of a polypeptide "capable of binding to IgE antibodies from an individual being allergic against mugwort pollen, wherein said polypeptide is selected from the group consisting of: (a) a polypeptide having an amino acid sequence that is at least 95% identical to the amino acid sequence as shown in SEQ ID NO:1; (b) a polypeptide comprising the amino acid sequence extending between residues 21 and 180 of SEQ ID NO:1; and (c) a polypeptide comprising the amino acid extending between residues 181 and 396 of SEQ ID NO:1." Support for this amendment is found in the specification and claims as originally filed, particularly at paragraphs [0005], [0016], and [0024] of the published application. This amendment is presented purely for the purposes of expediting prosecution and should not be interpreted as Applicants' agreement with any of the Examiner's positions.

- Claims 2 and 19 have been canceled as being now redundant of amended claim 1. This amendment is presented purely for the purposes of expediting prosecution and should not be interpreted as Applicants' agreement with any of the Examiner's positions.

- In accordance with the Examiner's suggestion, claims 3-4, 15, 18, and 20 have been amended to refer to "the allergen" rather than simply "allergen". As this amendment is presented for clarification purposes only, it should not be construed as a narrowing amendment presented for the purposes of patentability.

- New claims 38-40 are directly to particularly preferred embodiments of the elected invention. Support for these claims is found in the specification and claims as originally filed, particularly at paragraphs [0005] and [0016] of the published application.

Applicants respectfully submit that no new matter has been added. Moreover, Applicants respectfully submit that the instant response renders moot the outstanding claim rejections and places the instant application in condition for allowance. Further to this position, Applicants submit the following remarks:

Claim Objections - Minor Informalities

The Examiner objected to claims 1-4, 15, and 18-20 for including the following informalities:

(i) Claims 1-4 refer to "allergen" without a proper preceding article (e.g., "An allergen" or "The allergen"); and

(ii) Claim 3 fails to further limit the scope of claim 1 from which it depends.

With respect to item (i), to expedite prosecution, Applicants have canceled claim 2 and amended claims 1, 3, and 4 as discussed above. Applicants submit that such amendments render moot the Examiner's concerns and therefore request reconsideration and withdrawal of the objection to claims 1-4, 15, and 18-20.

With respect to item (ii), Applicants respectfully disagree with the Examiner's characterization. While the allergen of claim 1 consists of only a single polypeptide, that polypeptide has a sequence selected from the group consisting of: (a) an amino acid sequence that is at least 95% identical to SEQ ID NO:1; (b) an amino acid sequence comprising residues

21-180 of SEQ ID NO:1; and (c) an amino acid sequence comprising residues 181-396 of SEQ ID NO:1. Claim 3 further restricts the scope of claim 1 by requiring the polypeptide to comprise the entirety of the amino acid sequence as shown in SEQ ID NO: 1. Thus, Applicants respectfully submit that claim 3 is indeed in proper dependent form and, therefore, respectfully request reconsideration and withdrawal of the outstanding objection to claim 3.

Rejections under 35 U.S.C. § 101

Claims 1-4 and 19-20 stand rejected under 35 U.S.C. § 101 for being directed to non-statutory subject matter, namely a product of nature. The Examiner suggests that amending the claims to recite an "isolated" allergen would obviate the rejection.

So as to expedite prosecution, Applicants have herewith amended claim 1 in accordance with the Examiner's suggestion. Applicants respectfully submit that this amendment renders moot the outstanding rejection of claims 1-4 and 19-20 under 35 U.S.C. § 101 and, therefore, respectfully request reconsideration and withdrawal the rejection.

Rejections under 35 U.S.C. § 112, Second Paragraph

Claims 15 and 18-20 stand rejected under 35 U.S.C. § 112, second paragraph, for failing to particularly point out and distinctly claim that which constitutes the invention. Specifically, while claims 15 and 18-20 refer to "the polypeptide" of one of more of preceding claims 1-4, The Examiner finds there to be insufficient antecedent basis for this limitation because claims 1-4 are directed to an allergen rather than a polypeptide. The Examiner thus suggests that amending claims 15 and 18-20 to refer to the "allergen" would obviate the rejection.

So as to expedite prosecution, Applicants have herewith canceled claim 19 and amended claims 15, 18, and 20 in accordance with the Examiner's suggestion. Applicants respectfully submit that this amendment renders moot the outstanding rejection of claims 15 and 18-20 under 35 U.S.C. § 112, second paragraph and, therefore, respectfully request reconsideration and withdrawal of this rejection.

Rejections under 35 U.S.C. § 112, First Paragraph

Enablement:

Claims 1-4, 15, and 18-20 stand rejected under 35 U.S.C. § 112, first paragraph, for failing to comply with the enablement requirement. According to the Examiner, while the specification is enabling for an allergen consisting of SEQ ID NO: 1, it does not reasonably provide enablement for: (a) an allergen consisting of a polypeptide fragment comprising at least 18 consecutive amino acids from SEQ ID NO:1; (b) an allergen consisting of a polypeptide fragment capable of binding to IgE antibodies from individuals allergic to mugwort or ragweed pollen; (c) an allergen comprising the amino acid sequence of SEQ ID NO: 1; (d) a pharmaceutical composition comprising polypeptides as claimed; or (e) a kit for the prevention of an allergic disorder as claimed. The Examiner concludes that one skilled in the art would not be able to practice the invention as claimed without undue experimentation.

Applicants respectfully disagree. Nevertheless, in an effort to expedite prosecution, Applicants have amended claim 1 to recite "an isolated allergen consisting of a polypeptide capable of binding to IgE antibodies from an individual being allergic against mugwort pollen, wherein said polypeptide is selected from the group consisting of: (a) a polypeptide having an amino acid sequence that is at least 95% identical to the amino acid sequence as shown in SEQ ID NO:1; (b) a polypeptide comprising the amino acid sequence extending between residues 21 and 180 of SEQ ID NO:1; and (c) a polypeptide comprising the amino acid extending between residues 181 and 396 of SEQ ID NO:1." Applicants respectfully submit such amendment to claims 1 *et seq.* renders moot the Examiner's enablement concerns. To that end, Applicants direct the Examiner's attention to the enablement decision tree set forth in the "Training Materials For Examining Patent Applications With Respect To 35 USC § 112, First Paragraph - Enablement Chemical/Biotechnical Applications" first asks the question: "Does the specification teach how to make and use at least one embodiment encompassed by the claims as a whole without undue experimentation?" A note to the question states that "if there is a working example, the answer to the question cannot be 'NO'." Herein, Applicants not only provide general guidance as to how to make and use embodiments of the claimed invention but also describe at least three representative species that fall within the scope of the claimed invention (see paragraph [0016]). Accordingly, the answer to the first question is necessarily "YES".

The second question in the enablement decision tree is: "Are the enabled embodiments representative of the full scope of the claim?" As discussed in further detail below, the USPTO itself has deemed a single disclosed species to be representative of an analogous sequence variant encompassing genus. In this case, the high degree of sequence identity required by the claims yields structurally similar nucleotides; therefore, a person of skill in the art would not expect substantial variation among species within the genus. Accordingly, as Applicants have herein disclosed at least three representative species (i.e., SEQ ID NO: 1 as well as the 20-180 and 181-396 fragments thereof), the answer to this second question is necessarily "YES". Thus, following the guidelines of the enablement decision tree, no enablement rejection should be made under these circumstances. For these reasons, Applicants respectfully request reconsideration and withdrawal of the enablement rejection of claims 1-4, 15, and 18-20.

As to the Examiner's suggestion that without specific guidance as to which amino acids may be included and/or excluded, the experimentation left to those skilled in the art is undue, Applicants respectfully submit that the test for undue experimentation is not merely quantitative, since a considerable amount of experimentation is permissible, provided it is merely routine. See In re Wands 8 U.S.P.Q. 1400, 1404 (Fed. Cir. 1988). In this case, Applicants submit that the "trial and error" testing needed to identify the "core regions" protein is within the parameters of routine experimentation and optimization. Thus, Applicants submit that one of ordinary skill in the art would be able to practice the invention of the presently pending claims without undue experimentation.

As to the Examiner's assertion that Applicants' specification fails to enable *in vivo* utilities in the context of pharmaceutical applications, Applicants wish to remind the Examiner that the pending claims are directed to *compositions of matter* (i.e., allergens as well as kits, vectors, cells, and pharmaceutical compositions comprising such) and not *methods* of using same. Accordingly, the Examiner's discussion of unpredictability and the hurdles associated with achieving *in vivo* therapeutic results are not relevant to the issue of enablement of the claimed compositions. In fact, on the issue of "how to use", section 112, first paragraph, does not require a specification to enable *all* uses of the claimed invention; rather, a single disclosed or well-established use is all that is required. Furthermore, as noted in M.P.E.P. § 2164.01(c),

when a composition claim is not limited by a recited use, any enabled use that would reasonably correlate with the entire scope of that claim is sufficient to preclude a rejection for non-enablement based on how to use. If multiple uses for claimed compositions are disclosed in the application, then an enablement rejection must include an explanation, sufficiently supported by the evidence, why the specification fails to enable each disclosed use. In other words, if any use is enabled when multiple uses are disclosed, the application is enabling for the claimed invention. In this case, given the fact that Applicants have provided explicit working examples demonstrating the ability of the claimed embodiments to bind to IgE antibodies from subjects allergic to mugwort pollen and the diagnostic applications thereof, a rejection for lack of enablement is misplaced.

In addition, the Examiner's suggestion that "specific and detailed description" coupled with "working examples" is required seems to be in clear conflict with statutory and case law. For example, M.P.E.P. § 2107.01 and § 2107.03 clearly state that an applicant need not demonstrate that the invention is completely safe. Furthermore, under the current case law, Applicants need not prove clinical efficacy to show that a therapeutic process is operable (i.e., enabled). As stated in M.P.E.P. § 2107.01, the "courts have found utility for therapeutic inventions, despite the fact that an applicant is at a very early stage in the development of a therapeutic regimen" or that a therapeutic treatment regimen is not at a stage where it is ready to be clinically practiced. *Cross v. Iizuka*, 753 F.2d 1040, 224 U.S.P.Q. 739 (Fed. Cir. 1985); *In re Brana*, 51 F.3d 1560, 34 U.S.P.Q.2d 1436 (Fed. Cir. 1995). The guidelines further state that "[t]he Office must confine its review of patent applications to the statutory requirements of the patent law, and in quoting *In re Brana*, *supra*, that "FDA approval, however, is not a prerequisite for finding a compound useful within the meaning of the patent laws". *Id.*

Rather, the patent laws merely require that a "reasonable correlation" exist between the scope of the claims and the scope of enablement. If the art is such that a particular assay or model is recognized as correlating to a specific condition, then it should be accepted as correlating unless the examiner has evidence that the model does not correlate. In other words, the Examiner bears the burden for providing reasons supporting her conclusion of lack of correlation for an *in vitro* or *in vivo* animal model example. Importantly, a rigorous or an invariable exact correlation is not required. See *Cross v. Iizuka*, 753 F.2d 1040, 1050, 224 USPQ

739, 747 (Fed. Cir. 1985).

Thus, Applicants respectfully submit that the Examiner's allegations of a generic lack of guidance and unpredictability in the art are insufficient to support a conclusion that the presently claimed invention is not enabled for *in vivo* applications. In particular, given Applicants' conclusive demonstration that allergens of the present invention show clear and specific binding to mugwort pollen specific IgE antibodies and given that such positive *in vitro* findings are routinely correlated to positive *in vivo* findings, the burden is on the Examiner to demonstrate that one skilled in the art would not reasonably extrapolate the undisputed positive results to clinical therapy, a burden Applicants respectfully submit the Examiner has not met. Thus, Applicants submit that one of ordinary skill in the art would be able to practice the invention of the presently pending claims without undue experimentation with a reasonable expectation of success.

As to the Examiner's assertion that the instant specification fails to enable "prevention" of allergic disorders, Applicants respectfully submit that the Examiner's characterization of the term "prevent" as an absolute term is in error. According to www.wikipedia.org, "in medicine, prevention is any activity which reduces the burden of mortality or morbidity from disease". Prevention can occur "at primary, secondary and tertiary prevention levels." While "primary prevention avoids the development of a disease, secondary and tertiary levels of prevention encompass activities aimed at preventing the progression of a disease and the emergence of symptoms as well as reducing the negative impact of an already established disease by restoring function and reducing disease-related complications. Accordingly, Applicants respectfully submit that the term "prevent", when afforded its ordinary and customary meaning, does not necessarily equate to absolute cessation. Moreover, Applicants respectfully submit that one skilled in the art would readily recognize that, in the context of the instant claims, prevention encompasses a wide range of prophylactic therapies aimed at alleviating the onset or severity of one or more allergic symptoms. Thus, Applicants submit that one of ordinary skill in the art would be able to practice the invention of the presently pending claims without undue experimentation with a reasonable expectation of success.

In sum, in view of the amendments and remarks herein, Applicants respectfully request reconsideration and withdrawal of the enablement rejection of claims 1-4, 15, and 18-20.

Written Description:

Claims 1-4, 15, and 18-20 stand rejected under 35 U.S.C. § 112, first paragraph, for containing subject matter which was not described in such a way as to reasonably convey possession of the claimed invention. Specifically, while the Examiner accedes to Applicants' possession of an allergen consisting of SEQ ID NO:1, she challenges whether Applicants were in possession of an allergen (a) comprising a fragment of at least 18 consecutive amino acids of the amino acid sequence shown in SEQ ID NO: 1 or (b) comprising the amino acid sequence of SEQ ID NO: 1.

Applicants respectfully disagree. Nevertheless, in an effort to expedite prosecution, Applicants have amended claim 1 to recite "an isolated allergen consisting of a polypeptide capable of binding to IgE antibodies from an individual being allergic against mugwort pollen, wherein said polypeptide is selected from the group consisting of: (a) a polypeptide having an amino acid sequence that is at least 95% identical to the amino acid sequence as shown in SEQ ID NO:1; (b) a polypeptide comprising the amino acid sequence extending between residues 21 and 180 of SEQ ID NO:1; and (c) a polypeptide comprising the amino acid extending between residues 181 and 396 of SEQ ID NO:1. Applicants respectfully submit one of skill in the art would recognize that the Applicants were in possession of the necessary common attributes or features of the elements possessed by the members of the presently claimed genus in view of the representative species disclosed and guidance provided in the instant specification, coupled with conventional knowledge and level of skill in the prior art.

The standard for determining compliance with the written description requirement is "does the description clearly allow persons of ordinary skill in the art to recognize that he or she invented what is claimed." *In re Gosteli*, 872 F.2d 1008, 1012, 10 U.S.P.Q.2d 1614, 1618 (Fed. Cir. 1989). The standard for determining sufficiency of the description is "factual and depends on the nature of the invention and the amount of knowledge imparted to those skilled in the art by the disclosure." *In re Wertheim*, 541 F.2d at 262 (citing *In re Ruschig* 379 F.2d 990, 995-96 (C.C.P.A. 1967)). It is well accepted that a specification may, within the meaning of 35 U.S.C.

112, first paragraph, contain a written description of a broadly claimed invention without describing all species that the claim encompasses. The law does not require that the specification describe the exact details for preparing each and every species within the genus described. In fact, even if the Examiner considers the subject matter of the claims to be broader than that disclosed in the original specification, the written description requirement may be satisfied if the broader concept would naturally occur to one skilled in the art upon reading the earlier specification.

In this case, claim 1 encompasses a genus of allergen polypeptides defined in terms of both their specific relationship to disclosed SEQ ID NO: 1 (e.g., having an amino acid sequence at least 95% identical to SEQ ID NO: 1, comprising fragment extending between residues 21 and 180 of SEQ ID NO: 1, or comprising a fragment extending between residues 181 and 396 of SEQ ID NO: 1) as well as their functional properties (e.g. "capable of binding to IgE antibodies from an individual being allergic against mugwort pollen"). Applicants respectfully submit that allowance of a claim of this scope is in line with USPTO policy regarding written description analysis as set forth the Revised Interim Written Description Guidelines published January 5, 2001, particularly the Training Materials accompanying same (see http://www.uspto.gov/web/menu/written.pdf). Specifically, the Examiner's attention is directed to Example 14 of the Training Materials which analyzes a claim directed to variants of a protein that are at least 95% identical to a particular disclosed sequence and that have a particularly specified activity. Therein, the PTO concludes that "the genus of proteins that must be variants. . . *does not have substantial variation* since all the variants must possess the specific catalytic activity and must have at least 95% identity to the reference sequence". Thus, "the single species disclosed is representative of the genus because all members have at least 95% structural identity with the reference compound and because of the presence of an assay which applicant provides for identifying all of the at least 95% identical variants…which are capable of the specified catalytic activity." Accordingly, "one skilled in the art would conclude that applicant was in possession of the necessary common attributes possessed by the members of the genus" (i.e., the example claim meets the written description requirement of 35 USC § 112, first paragraph). See Training Materials, pages 53-55.

Applicants' amended claim 1 is analogous to the claim of Example 14 in that it is

directed to an isolated allergen consisting of a polypeptide having at least 95% identity to a reference sequence, namely, SEQ ID NO: 1, and having a specifically identified function, namely the ability to bind mugwort pollen IgE antibodies. As discussed above, since the species are defined both in terms of specific structure and specific function, the genus of polypeptides encompassed by the claim will not have substantial variation. Thus, it follows that since the genus is not widely variable, only a limited number of species [e.g., SEQ ID NO: 1 as well as the 21-180 and 181-396 fragments thereof] is needed to demonstrate possession. Furthermore, Applicants' specification sets forth assays for preparing and identifying suitable polypeptides capable of performing the specified function. See, for example, paragraph [0014] (assaying IgE binding); paragraphs [0016], [0022], and [0023] (identifying and manufacturing suitable variants); and paragraphs [0006] and [0024] (determining percent identity).

Thus, Applicants respectfully submit that the instant specification provides an adequate written description of the genus of polypeptide allergens encompassed by claims 1 *et seq.*, so as to convey with reasonable clarity to those skilled in the art that, as of the filing date sought, Applicants were in possession of the invention now claimed. Accordingly, Applicants respectfully request reconsideration and withdrawal of the written description rejection of claims 1-4, 15, and 18-20 in view of the amendments and remarks herein.

Rejections under 35 U.S.C. § 102

Claims 1-4, 15, and 19-20 stand rejected under 35 U.S.C. § 102(b) for being anticipated by Nilsen et al., Brandys et al., Hirschwehr et al., De La Hoz et al., Katial et al., or Paulsen et al. According to the Examiner, the prior art references disclose "an approximately 44 kDa polypeptide allergen in mugwort pollen that appears to be identical to Applicants' "Art v 6" protein (SEQ ID NO: 1). The Examiner finds the claimed structural and functional characteristics to be inherently taught by the prior art disclosures. Accordingly, the Examiner concludes that prior art references disclose or suggest and therefore anticipate the invention of claims 1-4 and 19-20.

Applicants respectfully disagree with the Examiner's characterization of the prior art disclosures. The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. *In re Rijckaert*, 9 F.3d

1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir.1993). Rather, to establish inherency, the extrinsic evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient. *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999). Thus, in relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art. *Ex parte Levy,* 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990)

In this case, Applicants submit that none of the "approximately 44 kDa polypeptide allergens isolated from mugwort pollen using SDS-PAGE gel" allegedly described by Nilsen et al., Brandys et al., Hirschwehr et al., de la Hoz et al., Katial et al. or Paulsen et al. is identical to the presently claimed polypeptide of SEQ ID NO: 1, referred to in Gen Bank Accession Number AY904433 as "Art v 6". Given the gaps in the prior art discussed in detail below and in the Rule 132 Declaration of Professor Fatima Ferreira provided herewith, Applicants submit that the evidence cited by the Examiner fails to make clear that the missing descriptive matter (i.e., the polypeptide of SEQ ID NO: 1) is necessarily present in the reference, and that it would be so recognized by persons of ordinary skill.

For example, although Nilsen et al. identified at least 15 IgE-binding components with molecular weights ranging from 12 kDa to 100 kDa, the authors provide no sequence information that would unequivocally prove that any of the isolated polypeptides is indeed identical to the polypeptide of SEQ ID NO: 1 (referred to herein as "Art v 6"). Moreover, none appear to have a molecular weight of 40,834.55 Daltons (see Figure 1 and Table 1) or a theoretical isoelectric point (pI) of 8.27 (see Figures 2-4).

Likewise, while Brandys et al. observed extract band patterns in the molecular weight region of 25 kDa to 90 kDa, the authors provide no sequence information that would unequivocally prove that any of the isolated polypeptides is indeed identical to the polypeptide of SEQ ID NO: 1. Moreover, none appear to have a molecular weight of 40,834.55 Daltons (see Figure 2) or a theoretical isoelectric point (pI) of 8.27 (see Figure 3).

With respect to the Hirschwehr publication, while the authors identified a number of allergenic structures common in mugwort and ragweed pollen, they provide no sequence information that would unequivocally prove that any of the isolated polypeptides is indeed identical to the polypeptide of SEQ ID NO: 1. Moreover, none appear to have a molecular weight of 40,834.55 Daltons (see Figures 1-3) or a theoretical isoelectric point (pI) of 8.27 (not shown).

With respect to the de la Hoz publication, Applicants respectfully submit that the authors' designation of the purified mugwort allergen as "Art v 1" is incorrect. In any event, the authors provide no sequence information that would unequivocally prove that the isolated polypeptide is indeed identical to the polypeptide of SEQ ID NO: 1. Furthermore, since under native conditions the protein was estimated to be 47,000 Da and under denaturing (SDS-PAGE) it was estimated to be 60,000 Da, the real molecular weight of the purified "Art v 1" protein is not known. In contrast, the polypeptide of SEQ ID NO: 1 (Art v 6) has a calculated molecular weight of 40,834.55 Da and under denaturing conditions (SDS-PAGE) it migrates as a 40,000 Da protein (see Figure 5 of the instant application). In addition, while analytical isoelectric focusing showed that the protein isolated by de la Hoz et al. is an acidic protein having a pI of 4.4, the polypeptide of SEQ ID NO: 1 is a basic protein with a pI of 8.2.

With respect to the Katial publication, while the authors utilized ELISA and IgE immunoblots to investigate cross-reactivity among mugwort (*Artemisia*) species, they provide no sequence information that would unequivocally prove that any of the isolated polypeptides is indeed identical to the polypeptide of SEQ ID NO: 1. In addition, while Katial et al. describe IgE-binding peptides in all extracts in the 66-kDa, 45-kDa, and 21-kDa ranges, they fail to specifically mention an IgE-binding protein in the range of 40-kDa.

With respect to the Paulsen publication, while the disclosed results indicate the presence of proteins in the MW region of 20,000-70,000, since no further purification of the individual components of the complex mixture or IgE-binding tests was performed, it cannot be said with any certainty whether any of the disclosed components are allergenic. In any event, the amino acid analysis of Paulsen's crude extract yields an amino acid composition that is quite distinct from that of the polypeptide of SEQ ID NO: 1 (see the amino acid content comparison set forth in Appendix B, attached hereto).

Thus, Applicants respectfully submit that none of the polypeptides described in the prior art are identical to the presently claimed ~40.9 kDa "Art v 6" protein defined by SEQ ID NO: 1. Since the cited prior art references fail to explicitly or inherently suggest each and every claimed element, Applicants submit that they cannot anticipate the invention of the pending claims. Accordingly, Applicants respectfully request reconsideration and withdrawal of the anticipation rejections of claim 1-4, 15, and 19-20 in view of the amendments and remarks herein.

Rejections under 35 U.S.C. § 103

Claim 19 stands further rejected under 35 U.S.C. § 103(a) for being obvious over Nilsen et al., Brandys et al., Hirschwehr et al., De La Hoz et al., Katial et al., or Paulsen et al., further in view of USPN 4,459,360. According to the Examiner, US '360 cures the deficiencies of the cited non-patent literature by disclosing a diagnostic kit for mugwort allergy screening. The Examiner thus concludes that it would have been obvious to one of ordinary skill in the art to package the "allergens" of the prior art in a kit as taught by US '360.

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir.1991). See M.P.E.P. § 2142, 2143.

Applicants respectfully submit that US '360 fails to cure the above-noted deficiencies of the Nilsen, Brandys, Hirschwehr, De La Hoz, Katial, and Paulsen references, namely the disclosure of an ~40.9 kDa "Art v 6" protein defined by SEQ ID NO: 1. Thus, in that the prior art references, alone or in combination, fail to teach or suggest all the claim limitations, Applicants respectfully submit that the Examiner has failed to set forth a *prima facie* case of obviousness. Accordingly, Applicants respectfully request reconsideration and withdrawal of the obviousness rejection of claim 19 in view of the amendments and remarks herein.

CONCLUSION

The outstanding Office Action set a three-month shortened statutory period for response. Pursuant to the entry of Applicants' petition for a one month extension of time, response is due on or before **December 3, 2007** (December 1, 2007 being a Saturday). Accordingly, Applicants submit that this response is timely and that no additional fee is required. However, in the event that further fees are required to enter the instant response and/or maintain the pendency of this application, the Commissioner is authorized to charge such fees to the undersigned's Deposit Account No. **50-2101**.

If the Examiner has any questions or concerns regarding this communication, she is invited to contact the undersigned.

Respectfully submitted,

Date: December 3, 2007

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